

United States Department of Agriculture Animal and Plant Health Inspection Service Plant Protection & Quarantine 4700 River Road Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil

Interstate Movement

Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME: Erika Rohr Luke PERMIT NUMBER: P526P-18-01450 ORGANIZATION: Marrone Bio Innovations APPLICATION NUMBER: P526-180102-041

ADDRESS: 1490 and 1530 Drew Avenue FACILITY NUMBER: 3576

Davis, CA 95618

MAILING ADDRESS: 1530 Drew Avenue HAND CARRY: No

Davis, CA 95618 **DATE ISSUED:** 04/17/2018

PHONE: 530-750-2800 DATE AMENDED: 12/18/2019 FAX: EXPIRES: 04/17/2021

DESTINATION: 1490 and 1530 Drew Avenue, Davis, CA

RELEASE: 95618

Under the conditions specified, this permit authorizes the following: Regulated Life Stage(s) **Intended Use Shipment Originally** Culture Designation <u>Article</u> **Origins** Collected Originally Collected N6, N1-5, N1-25, E6, Muscodor Lyophilized plant or MT Research albus microbes, Microbial Greenhouse (growth from Foreign and SA13, GBA, 620, 205, solutions, Mycelia, Petri chamber and lab Domestic Locations 100, 21, 105 and 5917A dishes/culture tubes included) MTOriginally Collected A3-5 Muscodor Lyophilized plant or Research microbes, Microbial Greenhouse (growth from Foreign and roseus Domestic Locations solutions, Mycelia, Petri chamber and lab dishes/culture tubes included) Muscodor Lyophilized plant or Research -Originally Collected Ca22 MT satura microbes, Microbial Greenhouse (growth from Foreign and solutions, Mycelia, Petri Domestic Locations chamber and lab dishes/culture tubes included) Muscodor spp.Lyophilized plant or Research -MT Originally Collected AR30 microbes, Microbial Greenhouse (growth from Foreign and solutions, Mycelia, Petri chamber and lab **Domestic Locations** dishes/culture tubes included)

PERMIT CONDITIONS

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Osmond Baron	12/18/2019



USDA-APHIS issues this permit to Erika Rohr Luke of Marrone Bio Innovations in Davis, California. This permit authorizes continued curation of the listed organisms received under prior permit, and the interstate movement of the listed regulated organisms from Montana.

This permit authorizes use of the regulated organisms for laboratory, growth chamber and restricted greenhouse research in the APHIS approved facility #3576. Plant inoculations using organisms that are listed at the genus level one on this permit are restricted to the laboratory and growth chambers.

1.

- This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
- The permit number or a copy of the permit must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable.
- not assign or transfer this permit to other persons without APHIS PPQ authorization,

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- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.
- Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.
- 3. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. Plant pathogen select agents currently listed include: *Peronosclerospora philippinensis (Peronosclerospora sacchari), Conothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia solanacearum, Rathayibacter toxicus, Sclerophthora rayssiae, Synchytrium endobioticum, and Xanthomonas oryzae.*
- 4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

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Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

- 5. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
- 6. Upon receipt, all packages must be opened within a Class II or III biosafety cabinet in the approved containment facility identified above to prevent the potential dissemination of the package contents. Cultures must be in a sealed container during transport to or within the permit holder's assigned research facilities.
- 7. All research activities, plant inoculations and subsequent disease development must occur within the APHIS approved Containment Facility identified above that has been inspected and found adequate for containment of the organisms received under this permit. Access to this facility must be restricted to authorized personnel.
- 8. Plant inoculations using organisms that are identified only to the genus level are restricted to the laboratory and growth chambers. Plant inoculations using organisms identified to the species level are authorized for plant inoculations in the laboratory, growth chambers, and greenhouse.
- 9. Greenhouses must be screened to minimize presence of insect vectors.
- 10. Standard Operating Procedures (SOPs) must be filed with, and approved by, the APHIS PPQ Pest Permit Staff at: email: pest.permits@aphis.usda.gov; phone: 866-524-54214700; fax: 301-734-8700; address: River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, permit conditions take precedence. APHIS PPQ must approve any changes to the SOPs before implementation.

A list of all persons with access to the containment facility must be maintained and available upon request by Federal or State Regulatory Officials.

11. Modifications to the containment facility or any changes that affect the containment of the regulated materials/organisms must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@aphis.usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).

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- 12. Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, and the date the isolate was received. These records must be made available to Federal and State regulators upon request.
- 13. When not working with the regulated materials/organisms, you must store and/or maintain them within the APHIS approved containment facility idenfied above. All stored regulated materials/organisms must be kept in a locked area with access limited to authorized personnel.
- 14. DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

All waste materials must be treated by one of the follow methods prior to disposal:

Use any of the following, either alone or in combination: 1) autoclaved (see protocol below), 2) disposed of as medical /biohazard waste with bonded contracted company (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5 percent sodium hypochlorite (household bleach from the bottle is 5 percent) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes. Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

Any equipment, supplies, tools, secondary shipping containers, packing materials (e.g, ice packs), etc. must be sterilized/sanitized/decontaminated prior to reuse, disposal, or removal from containment.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a written record must be maintained.
- d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250

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- Fahrenheit). You must follow the manufacturer's instructions. If any growth is observed, you must have the autoclave serviced and retested.
- 15. Devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.
- 16. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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